

**ROTARY ULTRASOUND SCANNER
FOR SOFT TISSUE EXAMINATION**

This application is a continuation of U.S. Patent Application No. 10/263,758 filed on October 4, 2002.

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION

[0001] The present invention relates in general to medical imaging systems and to a rotary ultrasound scanner for soft tissue examination for use in such systems.

DESCRIPTION OF THE PRIOR ART

[0002] Medical imaging is an important aspect in the practice of medicine. The use of medical imaging to assist in the diagnosis of patients has been well established over the years with different technologies being employed in scanning equipment. Current imaging technologies utilise x-rays, magnetic resonance imaging (MRI), ultrasound and other modalities to produce an image of the region of interest. However, each of these suffers from certain limitations in use. Technologies using x-rays require a limited use in a carefully controlled environment in view of the cumulative effect of radiation on the patient. Both MRI and x-ray imaging equipment are relatively immobile due to the large size of the scanning equipment. It is also frequently necessary to inject dyes (contrast media) into the patient to enhance visualisation, which, in turn, leads to the use of further specialized equipment.

[0003] The use of immobile specialized equipment makes it difficult to monitor patients frequently due to limited access to the equipment and the need to provide examination facilities. This biases the usage against frequent monitoring and evaluation of changes over time, which are particularly beneficial in the early detection of abnormalities.

[0004] The use of ultrasound devices in the examination of patients by medical practitioners has been a well-established practice since the 1950s. Ultrasound has proven to be useful in the field of medical imaging for soft tissue examination, particularly in detection of breast cancer in women. However, it has typically been used as an adjunct to mammography due to its limited scanning depth, lack of image resolution and amount of noise present in the acquired data.

Historically, ultrasound has been used post-mammography to determine whether masses in the breast are solid (requiring biopsy) or cystic (benign) but has not generally been considered to be useful in detecting masses in breast tissue that are smaller than 1 mm by 1 mm. The factors influencing this limitation are noise in the acquired data, the inability to replicate scans due to tissue deformation, and operator-dependant image interpretation. In practice, mammography has been found useful to detect microcalcifications as small as 0.3 mm. Microcalcifications generally start as small as 0.1 mm and are considered an early indication of a condition requiring ongoing monitoring.

[0005] Although there have been attempts to detect microcalcifications using ultrasound technology, it appears that most attempts have not succeeded. A discussion of ultrasound resolution can be found in the doctoral thesis of Sheila McFarland, UBC. In most of the prior art, it is believed that ultrasound is not capable of detecting microcalcifications with any degree of accuracy which has inhibited its utilisation on a broad basis.

[0006] However, the use of ultrasound does not require the elaborate safety precautions necessary with other imaging systems and therefore lends itself to frequent monitoring regimes. To be effective, a good coupling must be provided between the ultrasound transducer and the soft tissue and in some prior art scanners, the body part being examined has to be deformed prior to scanning to achieve this. This is partially to secure contact but primarily to manipulate tissues in the insonified area for best identification. Classic ultrasound may be considered a tissue manipulation practice performed with visual assistance. The deformation of the body part makes comparison of sequential images difficult, makes a read difficult to repeat and may lead to various masses being hidden from the scanner..

[0007] An ultrasound scanner for imaging breast tissue is disclosed in US Patent 6,005,916 to Johnson et al. and assigned to Techniscan Inc. This scanner utilises an annular array of transducers to interrogate an object placed within a water-filled chamber. The transducers in the annular array are operated sequentially to obtain a circumferential scan and the array is then moved vertically to perform a further scan. In this manner a 3 dimensional image may be obtained. The array may be adjusted circumferentially to adjust the position of the transducers relative to an object.

[0008] The scanner disclosed in the Johnson patent is relatively expensive due to its annular array and requires a complicated bladder arrangement for coupling the transducer to the fluid in

the examination chamber. Moreover, the Johnson patent is silent as to issues regarding repeatability of image capture such as is necessary to permit monitoring over an extended period.

[0009] It is an object of the present invention to mitigate or obviate at least one of the above-mentioned disadvantages.

SUMMARY OF THE INVENTION

[0010] In one aspect, the present invention provides a medical imaging system comprising a patient support surface. An imaging apparatus having a support table located within the support surface, and adjustable relative to the support surface to be located above the surface and thereby engage a portion of the patient to be imaged.

[0011] According to a further aspect of the present invention there is provided an ultrasound scanner assembly comprising a base, a drum rotating on the base. A transducer head rotating with the drum and displaced relative to the drum along an axis parallel to the axis of rotation. The head including a plurality of transducers each operable to propagate a wave along an axis of propagation and to receive signals from respective focal zones spaced relative to one another along the axis of propagation.

[0012] According also to the present invention there is provided a method of monitoring a medical condition through insonification with ultrasound by locating a portion of a patient on a scanner in a predetermined position to permit acquisition of data in a repeatable manner, conducting a succession of scans of the area of interest of the patient at predetermined intervals, transferring the scan to a remote location and comparing time separated scans to determine changes in said medical condition.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] An embodiment of the invention will now be described by way of example only with reference to the accompanying drawings in which:

[0014] Figure 1 is a schematic representation of components of a scanning system;

[0015] Figure 2 is a plan view of the system of Figure 1;

[0016] Figure 3 is a perspective view of a scanner assembly incorporated in the system of Figure 1;

[0017] Figure 4 is a side elevation of the scanner assembly of Figure 3;

- 1 [0018] Figure 5 is a detailed view of a portion of Figure 4.
- 2 [0019] Figure 6 is a functional block diagram of the controls used in the scanner assembly of
3 Figure 3;
- 4 [0020] Figure 7 is a schematic representation of the data acquired after one pass of the
5 scanner assembly of Figure 3;
- 6 [0021] Figure 8 is a flow chart representing the manipulation of data obtained from a pass of
7 the scanner assembly of Figure 3;
- 8 [0022] Figure 9 is a schematic representation of a complete signal produced by the
9 manipulation of data;
- 10 [0023] Figure 10 is a schematic representation of the data structure used in the manipulation
11 process of Figure 8; and
- 12 [0024] Figure 11 is a view of an interface used to control operation of the system of Figure 1.
13

14 DESCRIPTION OF THE PREFERRED EMBODIMENTS

- 15 [0025] As can be seen in Figures 1 and 2, an ultrasound scanning system 10 includes a
16 patient examination station 12 with a patient support surface 14. The surface 14 has an opening
17 16 to receive a table 18 formed by a lid 19 of a scanner assembly 20. The table 18 may be
18 covered with a soft or cushioning material to improve patient comfort in use if so required.
19 Scanner assembly 20 rests within a scanner case 22 located underneath the examination station
20 12. A remote computer 24, including a data acquisition software module 25, is connected to the
21 scanner 20 to receive data acquired during the operation of the scanner 20.
- 22 [0026] The scanner case 22 is supported on the floor and has an upper support base 26 to
23 receive the scanner assembly 20. A resilient support 28 is positioned between the assembly 20
24 and support base 26 to allow limited vertical movement between the base 26 and the assembly
25 20. An adjustment mechanism 30 is provided for the base 26 to allow vertical adjustment of the
26 base and thereby adjust alignment between the patient support surface 14 and the table 18 of the
27 scanner assembly 20. Any suitable adjustment mechanism may be used such as a rack and
28 pinion drive or a releasable cam and slide. The scanner assembly 10 is shown in greater detail in
29 Figures 3, 4 and 5.

1 [0027] The scanner assembly 20 includes a base 32 supporting a body 34. Body 34 has
2 sidewalls 36 that support the scanner lid 19 forming the table 18. An aperture 40 is provided in
3 the scanner lid 19 to receive a pendant breast of a patient prone on the support surface 14.

4 [0028] A drum 42 is rotatably supported on the base 32 by a spindle 44. The drum 42 has a
5 peripheral sidewall 46 and an end plate 48 supported on the spindle 44. The upper end 50 of the
6 sidewall is received in a recess 52 in the underside of the lid 19 around the aperture 40 to locate
7 the drum but allow rotation relative to the scanner lid 19.

8 [0029] A channel 54 is formed in the sidewall 46 parallel to axis of rotation. The channel 54
9 supports a transducer head 56 that is moveable along the channel 54 under the control of a drive
10 motor 58. The motor 58 is supported on the underside of the end plate 48 and drives a pair of
11 lead screws 60 through a toothed belt 62. The lead screws 60 support the transducer head 56 so
12 that rotation of the lead screws will provide translation of the transducer head 56 along the
13 channel 54. A switch 63 is located at an upper end of the channel 54 and is activated by the
14 transducer head 56 to indicate an upper limit of travel.

15 [0030] The spindle 44 supporting the drum 42 is driven by a motor 64 secured to the base
16 and driving the spindle 44 through a toothed belt drive 66 acting on a cog wheel 68. The spindle
17 44 also carries a rotary encoder 70, which consists of a disc 72 having alternating light and dark
18 sectors disposed around the periphery of the disc. An optical pick-up mechanism 74 is disposed
19 at the periphery of the encoder disc 72 to provide a signal indicative of rotation and position of
20 the drum 42. Each pulse of this signal marks a rotational increment. A resolution of 1800 marks
21 has been found to be satisfactory although other resolutions might be used. The encoder disc 72
22 also provides a zero home position indicator that allows a reference position for the disc to be
23 determined. The zero position is identifiable in the pulse train obtained from the encoder disc by
24 a unique pattern. Alternatively an absolute position encoder may be used to report a crisp
25 position pointer.

26 [0031] The transducer head 56 includes a substrate 80 (Figure 3) carrying three ultrasound
27 transducers 82, 84, 86. Each of the transducers is controlled by electronic circuitry indicated at
28 88 and carried on the end plate 48 of the drum 42. Data flow and control signals to and from the
29 transducers is transferred from the electronic circuitry 80 through slip rings 89 on the spindle 44
30 below the encoder disk 72 to a buffer and communication module 90 for transfer to the data
31 acquisition module 25 on the computer 24. It will be noted that the location of the circuitry 88 on

the rotating components enables the signals from the transducers to be processed without being subjected to the noise that may be introduced by the slip rings 89 and thereby enhance the extraction of information from the resultant signals.

[0032] The transducers 82, 84, 86 are each mounted on the substrate 80 such that their axis of propagation is inclined upwardly relative to the axis of rotation of the drum 44. As shown in Figure 5, the angle of inclination α , measured from the horizontal is selected so that the axis of propagation is generally orthogonal to the average tangent to the surface of a breast located in the drum 44. Typically an angle of 30° to the horizontal (i.e. 60° to the axis of the rotation) is found to be satisfactory although a range of 25° to 35° (55° to 65° to the axis of rotation) may be used.

[0033] Each of the transducers is also selected to provide different focal zones Z_1 Z_2 Z_3 which overlap along the axis of propagation. In a preferred embodiment transducers having a focal length of 30, 50 and 80 mm and with depths of field of 22-43mm; 14-87mm; and 44-140mm respectively are used with a drum diameter of 175 mm. The transducers have an operating frequency of 4.0 MHz. A sampling rate of 20MHz is preferred to provide an oversampling and resolution better than one half wavelength.

[0034] The functional blocks of the electrical circuitry 88 and buffer and communication module 90 are shown in Figure 6. The buffer and communication module 90 is provided on a standard parallel interface 100 for communication with the computer 24. Overall control of the scanner assembly is provided by a control and synch module 102 that receives operational parameters from the computer 24 as will be described more fully below. The control and synch module 102 initially sets the required gain of a main amplifier 104. Output from the main amplifier 104 is digitised by an A/D converter 118 and stored in a buffer 120 for communication over the interface 100.

[0035] A preamplifier 106 is associated with each of the transducers 82, 84, 86 and included in the circuitry 88 carried on the end plate 48. Input signals from the encoder 70 are processed through indexing function 107 and provided to the control and sync module 102. Module 102 generates a trigger pulse 108 at intervals defined by the operational parameters received from the computer 24 and transfers it across the slip ring 89 to a pulse multiplexer control module 110. The multiplexer control module 110 sequentially directs a trigger pulse signal 112 to a pulse circuit 114 associated with each of the transducers 82, 84, 86 respectively. The encoder 70 provides a pulse for each mark on the disc and, for maximum resolution, each pulse is used to

1 trigger one of the pulse circuits 114. Thus for an 1800 line encoder each of the transducers is
2 fired 600 times per revolution.

3 [0036] The reflected signal is received by the transducer and amplified by the corresponding
4 preamplifier 106 before being passed to a signal multiplexer 116. The signal multiplexer 116 is
5 switched by the module 102 after a predefined delay so as to receive the reflected signal in the
6 zone to be examined by the respective transducer. The delay is software adjustable depending on
7 the volume of tissue to be scanned but delays of 30 microseconds (μ s) are typical for the
8 exemplified apparatus. Multiplexer 116 passes the composite signal to the main amplifier 104.
9 The amplified signal is then digitised by A/D converter 118 and stored temporarily in buffer 120.
10 The contents of the buffer 120 are read prior to the data being overwritten with the output from
11 the next transducer and are downloaded through interface 100 to the data acquisition module 25
12 of the computer 24.

13 [0037] The control and synch module 102 is also operable to identify a zero or home position
14 on the encoder 70 and initiate operation of vertical drive motor 58 to displace the transducer head
15 56 by a selected distance upon completion of a circumferential scan.
16 Thereafter further scanning in a circumferential direction is performed.

17 [0038] As shown schematically in Figure 7, after one revolution, the data acquisition module
18 25 acquires data representing a set of conical slices S_1 , S_2 , S_3 made up of segments 124
19 representing the signals obtained from transducers 82, 84, and 86 respectively. Each subsequent
20 scan obtains data representing an additional set of slices displaced vertically from the previous
21 set to provide a set nested conical slices from which a three dimensional image may be
22 generated. The data acquisition module 25 receives data including the digitised reflected signal
23 received by each of the transducers and the circumferential and vertical position of the transducer
24 when the signal was received. Each of the data records, therefore is a representative of the
25 structure along respective segments 124 of the conical slices S_1 , S_2 , S_3 , shown in Figure 7. To
26 permit generation of a three dimensional image, the data in the data acquisition module 25 must
27 be manipulated as set out in the flow chart of Figure 8.

28 [0039] As an initial step 126, the slices S_1 , S_2 , S_3 are aligned circumferentially using the zero
29 reference signal obtained from the indexing function 107. As indicated in Figure 9, the segments
30 124 in one slice will be offset circumferentially from one segment in the adjacent slice due to the
31 rotation of the scanner assembly. The width of the insonifying beam produces a degree of

1 overlap between circumferentially adjacent segments 124 which increases as the segments 124
2 converge toward the apex of the cone. The circumferentially adjacent segments will therefore
3 contain common information and a comparison of the adjacent segments 124, indicated at 128 in
4 Figure 8, permits confirmation of a detected structure and removal of noise from the received
5 signal.

6 [0040] The segments 124 in each slice require further processing to take account of the
7 different gains established in preamplifiers 106 for each of the transducers 82, 84, 86. Due to the
8 overlapping between the focal zones the Z_1 , Z_2 , Z_3 of each transducer, a comparison indicated at
9 129 between the same signal in the overlapping portions may be used to produce a normalising
10 multiplier to provide a common basis for the signal in each segment.

11 [0041] Referring therefore to Figure 9, the segments 124 for the zones Z_1 and Z_2 overlap
12 radially as indicated at 130. The signal in each of the overlapping portions of the segments
13 should be representative of the same structure and therefore have the same value. To
14 compensate for signal attenuation, a weighting factor is applied as indicated by the trapezoidal
15 envelope's 131, 132 associated with zones Z_1 and Z_2 respectively. The signal of each segment is
16 sampled (134) at a number of locations in the overlapping portion 130 weighted (136) by the
17 appropriate envelope 131, 132 and a comparison made between the resulting values to obtain
18 (138) a ratio between the signals. The ratio is then applied (140) to one of the segments 124. A
19 similar process is repeated (142) in the overlap between Z_2 and Z_3 so that the three segments
20 representing the structure at a particular location are represented on a common basis.

21 [0042] The factored received signals obtained at step (140) are still influenced by the
22 attenuation of the beam as it passes through the insonified tissue. To compensate for the
23 attenuation in the direction of propagation, an average attenuation profile is obtained from the
24 factored signals as indicated in Figure 10.

25 [0043] Initially, the contour C_0 of the surface of the breast is located by examining each
26 composite received signal for the initial reflection. The detected contour C_0 is decreased by a
27 predetermined offset, dr , and the average signal about the circumference of the decreased
28 contour C_1 is obtained. The contour is further decreased by the offset dr and the average signal
29 C_2 is obtained. This is repeated along the path of the propagation to an inner value to obtain an
30 attenuation profile indicated in chain dot line based on the average signal. Once the profile is
31 determined, an inverse or reciprocal of the profile is obtained and a brightening algorithm

1 applied to the reformatted signals to obtain a normalised set of data representative of the
2 structure that has been insonified.

3 [0044] After each circumferential scan has been normalised, the data may then be converted
4 to a 3D Cartesian representation for display.

5 [0045] The software application implemented by the computer 24 includes a GUI interface,
6 shown in figure 11, permitting selection of the parameters required for the data acquisition and
7 identification of the patient, date and similar biographical data. The parameters selected include
8 gain control for each of the preamplifiers 106 to compensate for signal attenuation on a
9 transducer by transducer basis as indicated at 200; an adjustable delay period between pulse
10 control multiplexer and signal multiplexer to compensate for different tissue sample sizes;
11 adjustable amplification of the main amplifier 104 to compensate for tissue density fluctuations
12 between patients indicated at 202; adjustable vertical increments 204 at the head 56 to
13 accommodate different pathologic conditions and adjustable horizontal scan rate 206 to optimise
14 the data acquisition versus the time required to perform a scan. Each of these parameters is user
15 selectable on the GUI for a particular patient and transmitted to the control and synch module
16 102 prior to a scan being performed.

17 [0046] To perform a scan the drum 42 is filled with water such that upon placement of the
18 breast within the drum the water will be within a few mm of the top of the drum 42. A patient is
19 positioned on the patient support surface 14 and the scanner support base 26 adjusted so that the
20 table 18 is slightly proud of the support surface 14. The table 18 is positioned such that the
21 majority of the weight of the patient is taken by the support surface 14 but there is sufficient
22 pressure exerted on the table 18 by the patient to maintain a stable position and an acceptable
23 level of comfort. Relative movement between the scanner and patient due to breathing or bodily
24 movement is thus inhibited by the extra pressure exerted by the body. The patient's breast is
25 allowed to hang pendant within the water.

26
27 [0047] The patient's arm on the opposite side to the breast being examined may be placed
28 above their head to increase contact, improve comfort and reduce the compression of tissue
29 adjacent the chest cavity. After initial positioning, a visual check is made for correct positioning
30 and a preview or test scan is initiated to confirm a proper position. Once the correct position is
31 obtained, the patient is immobilised by padding and/or straps on the support surface 14.

[0048] To facilitate data acquisition and identification, a pair of presence transducers 122, typically either proximity or pressure transducers, are incorporated in the table 18 to either side of the aperture. The presence of the patient's sternum will be detected by one of the transducers 122 thereby indicating whether the left or right breast is being imaged.

[0049] The operating parameters are selected at the GUI and a scan initiated. The switch 63 ensures that the start position of head 56 is maintained for each scan. At each designated interval as identified by the encoder 70, the respective one of transducers 82, 84, 86 is pulsed and the reflected image received and processed. The overlapping focal zones Z_1 Z_2 Z_3 ensure a complete scan along the axis of propagation. The delay between propagation and receipt of the signal at each transducer ensures that the acquisition is performed in the region of interest for each transducer in turn and that the initial large reflected signal obtained during initial pulse firing is avoided. As seen in Figure 5, the signals processed are from distal portions of the path so that the signal attenuation is minimised over the observed depth of field. This permits the gain to be adjusted to obtain optimum signal strength and thereby enhance image acquisition and for each transducer to be adjusted for optimum imaging in its zone.

[0050] As can also be seen in Figure 5, the inclination of the transducers permits insonification of the breast above the portion immersed in water and beyond the drum. This permits interrogation of the chest tissue surrounding the breast, including the lymphatic system, and thereby provides a more comprehensive scan. The inclination of the transducer also brings the angle of incidence between the signal and surface of the breast closer to 90 degrees, to improve signal penetration and reconstruction

[0051] The circumferential scan may proceed either incrementally position by position or, preferably, on a continuous basis. The rate of scan may be modulated by adjusting the rotational speed of the drum 42 and the resolution adjusted by sampling at multiples of marks on the encoder 70. When the encoder 70 detects the zero position, a full rotation has been achieved and the transducer head 56 is displaced vertically along the Z-axis and the next scan (slice) begins.

[0052] The data acquisition continues until the full vertical scan is complete. The data acquired during scanning from each transducer represents a series of conical slices, which are reconstructed as described above to obtain a three-dimensional ultrasound image of the breast is thus obtained.

1 [0053] The image quality is enhanced by utilising distal portions of each of the ultrasound
2 signals and by pre-amplifying the received signals on the electronic circuitry 80 carried by the
3 drum and placed in immediate proximity to transducers. This amplification of signal reduces the
4 effect of noise inherent in transmission across the slip ring to result in an increased signal to
5 noise ratio and preserve.

6 [0054] The scanning system is relatively simple in construction and may be used without
7 specialised installation, supervision and safety measures. The patient support facilitates
8 repeatable image scans. Thus, although a single image may be obtained, the scanner assembly
9 may also be used to obtain images on a periodic basis under comparable imaging conditions.
10 The periodic images can then be compared and changes in detected structure noted. The
11 computer 26 may be remote from the scanning apparatus so that data acquisition may be
12 performed over a telephone connection or similar communication line. If preferred, a
13 communication module may be incorporated into the base allowing the scanner to function as a
14 client in a LAN or other network. In this manner the comparison of images may be performed
15 remotely and the image parameters adjusted remotely to enhance data acquisition. The provision
16 of the network capability also permits multiple scanners to be controlled from a single operator
17 workstation and for data to be acquired and processed centrally.

18 [0055] The system is designed for non-real time analysis, remote analysis and time series
19 analysis. The support system permits the patient to be scanned in a non-deformed
20 "configuration", where the breast is placed in such a way as to allow for a reasonable ability to
21 repeat the breast position from scan to scan over time. This allows for the scans to be mapped to
22 each other and enables the diagnostician to compare scans and determine whether any changes
23 are occurring in the tissue. The apparatus facilitates the acquisition of such scans in a home or
24 clinic environment with remote monitoring and diagnosis. If further investigation is warranted it
25 may be performed on the same apparatus under different operating parameters, e.g. resolution, or
26 as an alternative form of scan at a specialised facility.

27 [0056] Although, the system has been described with a breast-imaging scanner, it will be
28 appreciated that it may be adapted for other soft tissue imaging with appropriate modification to
29 the drum and pertinent support.
30
31